

**Appendix B**  
**Clean Copy of Pending Claims Without Markings**

19. The composition according to claim 21, wherein the recombinant AAV comprises a constitutive promoter.

20. The composition according to claim 19, wherein the promoter is selected from the group consisting of the cytomegalovirus immediate early promoter and the Rous sarcoma virus LTR promoter.

21(Four Times Amended). A composition comprising a recombinant adeno-associated virus (AAV) suspended in a biologically compatible carrier,  
wherein said recombinant AAV comprises (a) 5' AAV inverted terminal repeats (ITRs), (b) nucleic acid sequences encoding human apolipoprotein E (ApoE) operably linked to regulatory sequences which direct its expression, and (c) 3' AAV ITRs, and

wherein the recombinant AAV is at least as free of contaminating adenoviral helper virus as is obtained by subjecting said recombinant AAV to four rounds of cesium chloride gradient centrifugation.

22. The composition according to claim 21, wherein said composition comprises at least  $10^9$  particles of recombinant AAV.

23. The composition according to claim 21, wherein the composition comprises  $2.5 \times 10^{10}$  to  $5 \times 10^{10}$  genomes of recombinant AAV.

24. The composition according to claim 21, wherein the composition comprises  $5 \times 10^{10}$  to  $5 \times 10^{11}$  genomes of recombinant AAV.

26. A method of delivering apolipoprotein E (ApoE) to a mammal with atherosclerosis, said method comprising the step of administering to the mammal a composition comprising a recombinant adeno-associated virus (AAV) suspended in a biologically compatible carrier,
- wherein said recombinant AAV comprises (a) 5' AAV inverted terminal repeats (ITRs), (b) nucleic acid sequences encoding human apolipoprotein E (ApoE) operably linked to regulatory sequences which direct expression thereof and (c) 3' AAV ITRs, wherein the recombinant AAV is at least as free of contaminating adenoviral helper virus as is obtained by subjecting said recombinant AAV to four rounds of cesium chloride gradient centrifugation and wherein the ApoE in said composition is expressed in the mammal.
27. The method according to claim 26, wherein said recombinant AAV is administered intramuscularly.
28. The method according to claim 26, wherein said composition comprises at least  $10^9$  genomes of recombinant AAV.
29. The method according to claim 26, further comprising the step of monitoring the mammal for expression of ApoE.

30. A method of delivering apolipoprotein E (ApoE) to a mammal with atherosclerosis, said method comprising the step of administering to the mammal a composition comprising a recombinant adeno-associated virus (AAV) suspended in a biologically compatible carrier intramuscularly, wherein said recombinant AAV comprises (a) 5' AAV inverted terminal repeats (ITRs), (b) nucleic acid sequences encoding human apolipoprotein E (ApoE) operably linked to regulatory sequences which direct expression thereof and (c) 3' AAV ITRs, wherein the rAAV is at least as free of contaminating adenoviral helper virus as is obtained by subjecting said recombinant AAV to four rounds of cesium chloride gradient centrifugation and wherein the ApoE in said composition is expressed in the mammal.

31. The method according to claim 30, wherein the composition is administered into the skeletal muscle.

32. The method according to claim 30, further comprising the step of monitoring the mammal for expression of ApoE.

33 (New). The method according to claim 30, wherein the level of contaminating adenoviral helper virus is the same as that obtained by subjecting said recombinant AAV to four rounds of cesium chloride centrifugation.

34 (New). The composition according to claim 21, wherein the level of contaminating adenoviral helper virus is the same as that obtained by subjecting said recombinant AAV to four rounds of cesium chloride centrifugation.